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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/980,999 | 05/20/2002 | Philip Braithwaite | 2245/107 | 3300 |
| 2101 | 7590 | 02/06/2004 | EXAMINER | |
| BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618 | | | WEISS JR, JOSEPH FRANCIS | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |
| DATE MAILED: 02/06/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/980,999 | BRAITHWAITE, PHILIP |
| | Examiner | Art Unit |
| | Joseph F Weiss Jr. | 3743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. If applicant is attempting to invoke 112(6) with a sealing means recitation directed what the moisture proof barrier is, then it is possibly a broadening of claim 1's recitation of the moisture proof barrier comprising a resilient sealing member in a fixed position, if this is in addition to the limitations of claim 1 on this element then it may be proper, but still likely unclear.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 2, 5, 17 & 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 5 recites the limitation "the sealing means" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
4. Claim 5 recites the limitation "the end" in line 2. There is insufficient antecedent basis for this limitation in the claim.

IN regards to claim 2, applicant further defines the moisture proof barrier as being a moisture proof sealing means, or a "means for sealing" appears to be an

invocation of 112(6), but being that the moisture proof barrier is also set forth as a resilient sealing member in a fixed position then, this limitation takes it out of 112(6). Applicant may wish to reverse the presentation of the limitation of claims 1 & 2 in regard to what is the moisture proof barrier to resolve this issue.

Claim 17 recites the limitation "the medicament" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the second member" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Also in regards to claim 18, applicant sets forth that the air duct provides a flow of air through "the passage" and the cup into the inhalation passage upon operation of the device, i.e. it passes twice through the passage? Only one passage is set forth, thus this redundancy creates a lack of definiteness.

5. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. See MPEP 2173.05(r).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1-9, 15-23 & 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Dmitrovic PCT WO98/30262).

In regards to claim 1, Dmitrovic discloses a medicament delivery device comprising a medicament reservoir (56), a medicament delivery passage (11), a metering member (3/22) adapted to transfer a measured dose of medicament from the medicament reservoir to the delivery passage, the device being provided with a moisture proof barrier that comprises a resilient sealing member in a fixed position. (10, 51 or 51a and its interface to form the dynamic seal depending upon the embodiment/fig).

In regards to claim 2, Dmitrovic discloses the moisture proof barrier as being a moisture proof sealing means.

In regards to claim 3, Dmitrovic discloses the moisture proof barrier being positioned to prevent the ingress of moisture into the medicament reservoir.

In regards to claim 4, Dmitrovic discloses the sealing means as being adapted to move from an inoperable position where the medicament reservoir is sealed and an operable position in which the seal is broken so that measurement/delivery of a dose of medicament occurs.

In regards to claim 5, Dmitrovic discloses the sealing means comprising a resilient sealing member positioned at the end of the medicament reservoir adjacent the metering member (10, 51 or 51a).

In regards to claim 6, Dmitrovic discloses the metering member being biased toward the sealing member.

In regards to claim 7, Dmitrovic discloses an inhaler.

In regards to claim 8, Dmitrovic discloses a dry powder inhaler.

In regards to claim 9, Dmitrovic discloses the metering member as being operable from a operable position to an inoperable position.

In regards to claim 10, Dmitrovic discloses the metering member (3/22) comprising a combination of a dispensing member (22) and an outer sleeve (3).

In regards to claim 11, Dmitrovic discloses the sleeve as being moisture resistant (note the interface of 3 & 10).

In regards to claim 12, Dmitrovic discloses the moisture resistant sleeve is adapted to act as a medicament measuring device.

In regards to claim 15, Dmitrovic discloses a medicament delivery device which is an inhaler and comprises a medicament reservoir (56), an inhalation passage (7), and a metering member (3) provided with at least one dispensing cup (22) and adapted to transfer a measured dose of medicamnt from the medicament reservoir to the inhalation passage, where the dispensing cup is provided with an air duct (8).

In regards to claim 16, Dmitrovic discloses an inhaler that is provided with a moisture proof barrier (10, 51 or 51a & its dynamic seal).

In regards to claim 17, Dmitrovic discloses an inhaler comprising a medicament reservoir (56) an inhalation passage (7) for the delivery of medicament and a metering member (11/22) adapted to transfer a measured dose of medicament from the reservoir to the inhalation passage wherein the metering member comprises a measuring member (22) adapted to measure a pre-defined dosage of medicament and movable from a measuring to a non-measuring position, and a dispensing member (3) adapted to receive the measured dosage of medicament from the measuring member to deliver the

medicament to the inhalation passage, the dispensing member being movable from a medicament receiving position to a medicament delivering position.

In regards to claim 18, Dmitrovic discloses the dispensing member as having at least one medicament receiving cups (22) and being provided with an air duct (8) so as to provide a flow of air through the duct and the cup into the inhalation passage upon operation of the device.

In regards to claim 19, Dmitrovic discloses an inhaler comprising a medicament reservoir (56), an inhalation passage way for the delivery of the medicament (7) and a metering member (3/22) adapted to transfer a measured dose of medicament from the medicament reservoir wherein the metering member is provided with a duct (8) to allow air to be sucked through the metering member upon inhalation by the patient.

In regards to claim 20, Dmitrovic discloses that the metering member comprises an outer sleeve (3) and a dispensing member (22).

In regards to claim 21, Dmitrovic discloses the duct (8) is part of the measuring cup in the dispensing member (by dint of being defined by element 3 which also defines the measuring cup).

In regards to claim 22, Dmitrovic discloses a method of administering medicament by inhalation, which comprises the use by the patient of an inhaler IAW claim 1.

In regards to claim 23, Dmitrovic discloses a method of administering dry powder medicament by using an inhaler IAW claim 7.

In regards to claim 25, due to the significant lack of definiteness art cannot be applied to this omnibus claim

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 13-14 & 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic.

In regards to claim 13, Dmitrovic discloses, the reference noted above substantially disclose the claimed invention except for the shape of a frusto-hemispherical cone.

It is noted that applicant's specification does not set forth this shape, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, Dmitrovic discloses to include a two step dosing operation, the reference noted above substantially disclose the claimed invention except for a three step dosing operation.

It is noted that applicant's specification does not set forth such an intended result, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 24, Dmitrovic discloses a method of treating a respiratory disorder, which is fully capable of using a combination of medicaments within an inhaler IAW claim 7.

10. Claim 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic in view of Braithwaite (US 5657748).

Dmitrovic substantially discloses the instant application's claimed invention, but does not explicitly disclose a frusto-conical hemispherical shape. However, Braithwaite disclose such (6). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Braithwaite and used them with the device of Dmitrovic. The suggestion/motivation for doing so would have been to optimize medicament delivery. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of

design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dmitrovic & Braithwaite as applied to claim 13 above, and further in view of Newhouse (US 5113855).

The suggested device substantially discloses the instant application's claimed invention, but does not explicitly disclose a three step dosing action/operation. However, Newhouse disclose such (see fig 5-9 & supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Newhouse and used them with the suggested device. The suggestion/motivation for doing so would have been to optimize drug delivery. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Conclusion

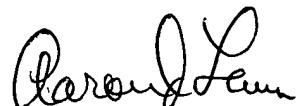
12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6557550, 6553987, 6484718, 6321747, 6220243, 6116239, 6065471, 5678538, 5575280, 5437270, 53948685320714, 5201308, 5161524

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JF Weiss
2/3/04


Aaron J. Lewis
Primary Examiner